K120072

510(k) Summary

MAY - 8 2012

Submitter:	Edwards Lifesciences LLC
Contact Person:	Karen Jones, Senior Manager, Regulatory Affairs 12050 Lone Peak Pkwy Draper, UT 84020 (801) 565-6231
Date Prepared:	January 9, 2012
Trade Name:	Edwards Lifesciences® Venous Drainage Cannulae
Classification Name:	Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass 21 CFR Part 870.4210, Product Code DWF, Class II
Predicate Device:	K831769 - Venous Cannulae K033464 - Pediatric Venous Cannulae K092509 – Venous Cannulae

Device Description:

Edwards Lifesciences venous return cannulae are soft cannulae with encapsulated steel wire reinforcement. Venous return cannulae are offered with various tip styles, hole patterns, French sizes, lengths, straight or angled tubing, and two sizes of connectors. Some styles are offered with obturators.

The exterior and inner-luminal cannula surfaces of product codes containing a "D" or "DII" are coated with Duraflo heparin. When used on devices for cardiopulmonary surgery, the Duraflo coating improves the blood compatibility of non-biological surfaces in the extracorporeal circuit.

Each Edwards Lifesciences device is packaged sterile and non-pyrogenic in a sealed, peel-type pouch.

Indications for Use:

Single Stage Venous Cannulae:

Venous return cannulae are intended for cannula drainage from the right atrium or superior and inferior vena cava during extracorporeal circulation for a duration of ≤6 hours.

Venous cannulae may be used in pediatric populations or adult populations based on flow rate requirements and patient anatomy. Please see labeling for maximum flow rate information.

Extracorporeal circuit components with a Duraflo coating are intended for use in cardiopulmonary surgery when a heparin coated blood path is desired.

Dual Stage Venous Cannulae:

Dual drainage venous return cannulae are indicated for venous cannulation so that extracorporeal circulation of the venous blood to a heart-lung machine may be achieved, for a duration of ≤6 hours.

Venous cannulae may be used in pediatric populations or adult populations based on flow rate requirements and patient anatomy. Please see labeling for maximum flow rate information.

Extracorporeal circuit components with a Duraflo coating are intended for use in cardiopulmonary surgery when a heparin coated blood path is desired.

Comparative Analysis:

The subject devices with revised Indications for Use statements have the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate devices. It has been demonstrated that the subject Venous Drainage Cannulae are comparable to the predicate devices in fundamental scientific technology, material types, principles of operation, and functional performance evaluations. No new issues of safety or efficacy have been raised.Conclusion:

The Venous Drainage Cannulae are substantially equivalent to the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY - 8 2012

Edwards Lifesciences, LLC.
c/o Ms. Karen Jones
Sr. Principal Project Manager, Regulatory Affairs
12050 Lone Peak Parkway
Draper, UT 84020

Re: K120072
Venous Drainage Cannulae
Regulation Number: 21 CFR 870.4210
Regulation Name: Vascular Catheter, Cannula or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: March 26, 2012
Received: March 27, 2012

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K120072

Device Name: Edwards Lifesciences® Single Stage Venous Cannulae
Edwards Lifesciences® Dual Stage Venous Cannulae

Indications for Use:

Single Stage Venous Cannulae:

Venous return cannulae are intended for cannula drainage from the right atrium or superior and inferior vena cava during extracorporeal circulation for a duration of ≤6 hours.

Venous cannulae may be used in pediatric populations or adult populations based on flow rate requirements and patient anatomy. Please see labeling for maximum flow rate information.

Extracorporeal circuit components with a Duraflo coating are intended for use in cardiopulmonary surgery when a heparin coated blood path is desired.

Dual Stage Venous Cannulae:

Dual drainage venous return cannulae are indicated for venous cannulation so that extracorporeal circulation of the venous blood to a heart-lung machine may be achieved, for a duration of ≤6 hours.

Venous cannulae may be used in pediatric populations or adult populations based on flow rate requirements and patient anatomy. Please see labeling for maximum flow rate information.

Extracorporeal circuit components with a Duraflo coating are intended for use in cardiopulmonary surgery when a heparin coated blood path is desired.

Prescription Use __x__ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K120072